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Docket No. 218025US34PCT

IN RE APPLICATION OF: Silvio DEL FLORA, et al.  
SERIAL NO: 09/125,022

FILED: November 24, 1998

FOR: PHARMACEUTICAL COMPOSITION ENABLING TO INHIBIT CANCER METASTASIS FORMATION  
CONTAINING N-ACETYL-CYSTEINE AND DOXORUBICINASSISTANT COMMISSIONER FOR PATENTS  
WASHINGTON, D.C. 20231

SIR:

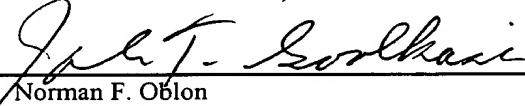
Transmitted herewith is an amendment in the above-identified application.

- No additional fee is required
- Small entity status of this application under 37 C.F.R. §1.9 and §1.27 is claimed.
- Additional documents filed herewith: Marked-up copy of amendments

The Fee has been calculated as shown below:

| CLAIMS      | CLAIMS<br>REMAINING |  | HIGHEST<br>NUMBER<br>PREVIOUSLY<br>PAID | NO. EXTRA<br>CLAIMS | RATE     | CALCULATIONS |
|-------------|---------------------|--|---|---------------------|----------|--------------|
| TOTAL       | 5                   | MINUS  | 20                                      | 0                   | × \$18 = | \$0.00       |
| INDEPENDENT | 1                   | MINUS  | 3                                       | 0                   | × \$84 = | \$0.00       |
|             |                     | <input type="checkbox"/> MULTIPLE DEPENDENT CLAIMS                   |   | + \$280 =           |          | \$0.00       |
|             |                     |  |   |                     |          | \$0.00       |
|             |                     | <input type="checkbox"/> Reduction by 50% for filing by Small Entity |   |                     |          | \$0.00       |
|             |                     | <input type="checkbox"/> Recordation of Assignment                   |   | + \$40 =            |          | \$0.00       |
|             |                     |  |   |                     |          | TOTAL        |
|             |                     |  |   |                     |          | \$0.00       |

- A check in the amount of \_\_\_\_\_ is attached.
- Please charge any additional Fees for the papers being filed herewith and for which no check is enclosed herewith, or credit any overpayment to deposit Account No. 15-0030. A duplicate copy of this sheet is enclosed.
- If these papers are not considered timely filed by the Patent and Trademark Office, then a petition is hereby made under 37 C.F.R. §1.136, and any additional fees required under 37 C.F.R. §1.136 for any necessary extension of time may be charged to Deposit Account No. 15-0030. A duplicate copy of this sheet is enclosed.

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218025US34PCT



IN THE UNITED STATES PATENT & TRADEMARK OFFICE

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IN RE APPLICATION OF:

DE FLORA, ET AL. : EXAMINER: HOWARD V. OWENS, JR.

SERIAL NO: 09/125,022

FILED: November 24, 1998 : GROUP ART UNIT: 1623

FOR: PHARMACEUTICAL COMPOSITION ENABLING TO INHIBIT CANCER  
METASTASIS FORMATION CONTAINING N-ACETYL-CYSTEINE AND  
DOXORUBICIN

AMENDMENT

ASSISTANT COMMISSIONER FOR PATENTS  
WASHINGTON, D.C. 20231

SIR:

In response to the Examiner's Office Action dated December 19, 2001, kindly amend the above-identified application as follows (marked-up copy of amendments attached):

IN THE CLAIMS

--13. (Twice amended) A method for inhibiting the formation of metastases in a patient having a primary cancerous tumor, which has not yet metastasized but is capable of metastasizing, the method comprising administering to said patient N-acetyl-cysteine and doxorubicin together in a synergistic mixture or individually in amounts and within such a period as to act synergistically together to produce a cancer metastasis formation inhibiting effect.

16. (New) The method according to Claim 13, wherein said doxorubicin is administered intravenously.